Exhibit 1

State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.

Exhibit to the Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Summary Judgment as to Defendant Mylan

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DECLARATION OF J. KEVIN GOROSPE

I, J. Kevin Gorospe, do hereby declare as follows:

1. My name is J. Kevin Gorospe. I am currently employed as the Chief of Medi-Cal Pharmacy Policy, California Department of Health Care Services ("DHCS"). I have been employed with the DHCS since 1995. I have personal knowledge of the matters stated in this declaration, and if called to do so, could competently testify thereto.

2. The purpose of this declaration is to provide evidence in support of California's Motion for Summary Judgment in the above-captioned action, *State of California, ex rel. Ven-a-Care of the Florida Keys, Inc., et al. v. Abbott Laboratories, Inc., et al.* The "Relevant Time Period" for this action is January 1, 1994 through December 31, 2004. I understand that this motion is directed to three of the four remaining defendants in this action, defendants Dey, Mylan, and Sandoz (collectively, the "defendants"). I further understand that California's action against the defendants concerns only certain drugs, the "Subject Drugs," which are specifically identified by their respective NDCs.

3. Since at least January 1, 1994, and throughout the Relevant Time Period, California's state Medicaid program, Medi-Cal, has included a fee-for-service prescription drug

program that reimburses Medi-Cal providers for the prescription drugs they dispense to Medi-Cal beneficiaries. During the Relevant Time Period, pharmacies and other Medi-Cal providers routinely submitted pharmaceutical claims to Medi-Cal for reimbursement of the defendants' Subject Drugs that the providers had dispensed to Medi-Cal beneficiaries. Medi-Cal paid each of these claims for the defendants' Subject Drugs with government funds.

4. Throughout the Relevant Time Period, California has required Medi-Cal providers to submit their claims to Medi-Cal's fiscal intermediary, Electronic Data Systems ("EDS"), for processing and payment. The reimbursement process is complex, made more so by the sheer volume of claims submitted by providers. Medi-Cal routinely processes and pays over 1 million claims per week.

5. Pursuant to applicable statutory and regulatory requirements, throughout the Relevant Time Period provider claims were adjudicated and paid at the lesser of the provider's Usual and Customary Charge or at the sum of the Cost of the Drug Product and the Medi-Cal dispensing fee.

a. Throughout the Relevant Time Period, the reimbursement amount for drugs reimbursed at the provider's Usual and Customary Charge was defined as the charge that providers charged the general public for prescription drugs. The provider's Usual and Customary Charge is an amount that combines a charge for the drug and a charge for the act of dispensing the drug, generally referred to as a dispensing fee.

b. Throughout the Relevant Time Period, the reimbursement amount for drugs reimbursed at the Cost of a Drug Product was the lowest of (a) the product's Estimated Acquisition Cost ("EAC"); (b) the state's Maximum Allowable Ingredient Cost ("MAIC") for the product; or (c) the product's Federal Allowable Cost ("FAC," a/k/a Federal Upper Limit

"FUL"). California's EAC has been established at various times as Direct Price ("DP") or, as is relevant to the remaining defendants and their Subject Drugs, AWP less a certain percentage discount—*viz*., less 5% from at least January 1, 1994 through November 2002; less 10% from December 2002 through August 2004; and less 17% from September 2004 through the present.

6. When reimbursed at the Cost of the Drug Product, Medi-Cal paid providers an additional and separate dispensing fee, which throughout the Relevant Time Period was fixed at $4.05 per provider claim from at least January 1, 1994 through August 31, 2004; and then $7.25 (or $8.00 for nursing facilities) per provider claim from September 1, 2004 through the present. When reimbursed at the provider's Usual and Customary Charge, the provider's billed amount to Medi-Cal included the dispensing fees. By statute, the total payment to the providers was then reduced by an amount varying over time from 10¢ to 50¢ per claim.

7. Throughout the Relevant Time Period, EAC in California was established on an NDC-by-NDC basis, and it has been based exclusively on the pricing information that the defendants published and/or have caused to be published in First Data Bank ("FDB"), a drug-pricing compendia commonly used by Medicaid programs and other third-party payors throughout the country.

8. I am aware that a minority of state Medicaid programs reimburse providers on the basis of the Wholesale Acquisition Cost ("WAC"), a common pricing metric that, like AWP, is reported by manufacturers to pricing compendia like FDB. It was not Medi-Cal's regular practice to monitor WAC prices during the Relevant Time Period.

9. I am aware that at various times throughout the instant litigation, the defendants have suggested that Medi-Cal could and should have utilized AMP information provided to the federal government for purposes of establishing reimbursement policy and, more particularly,

setting reimbursement rates. However, due to their federally-mandated confidentiality and the federal proscription against using AMP information for these purposes, and because California rarely received any AMP information for generic drugs from any source, using AMPs as a basis for setting reimbursement policy or rates would have been practically impossible during the Relevant Time Period.

Furthermore, as has long been commonly understood by many involved with third-party reimbursement for prescription drugs, AMPs bear little relationship to actual market prices for prescription drugs. This is due to the fact that AMPs can fluctuate significantly from month-to-month, and because they can often be lower than the prices widely available to purchasers. Moreover, AMPs can be restated and retroactively applied after being reported to the federal government, as was often true of some manufacturers for almost any quarter during the Relevant Time Period. I am aware that a pharmaceutical manufacturers' trade group identified as the Generic Pharmaceutical Association (of which defendant Mylan is a member) has adopted and promoted a similarly unfavorable view with respect to the use of AMP as a metric for purposes of third-party prescription drug reimbursement.

Given the foregoing, at no time before or during the Relevant Time Period did Medi-Cal use AMPs to determine prescription drug reimbursement rates, nor did it use them as a basis for paying provider claims.

10. Unit Rebate Amount ("URA") is a term used to identify the federal rebate owed by manufacturers on a per-unit basis to both the states and federal government. Throughout the Relevant Time Period, Medi-Cal administered, invoiced, processed, and collected the rebates owed by manufacturers pursuant to statute. With respect to these federal rebates, the federal government provided each drug's URA to Medi-Cal so that Medi-Cal, through its fiscal

intermediary, EDS, could adjudicate the appropriate federal rebate on a per-unit basis. As a result, Medi-Cal often had access to URA information with regard to drugs for which a federal rebate was owed. I am aware that the defendants have at various times throughout the course of the instant litigation suggested that for generic drugs, Medi-Cal could and should have "reverse engineered" the AMP for each of the drugs on the Medi-Cal formulary by dividing each URA by 11 percent (the fixed rebate percentage established by federal law for generic drugs) and then compare the derived AMP to manufacturer-reported AWPs. However, given the sheer number of URAs and claims submitted to Medi-Cal on a weekly basis, cross-verifying the AWP prices submitted by manufacturers to FDB against a calculated figure based upon a reverse-engineered AMP derived through each drug's URA would have proven so tremendously burdensome on DHCS's limited resources, that it would have been practically impossible. Moreover, in some instances during the Relevant Time Period, the federal government did not provide a URA to Medi-Cal for certain NDCs because either the manufacturer did not report an AMP as required, or because the federal government had some questions about the AMP that was reported. Furthermore, because California was prohibited from using AMP information for the purposes of establishing reimbursement policy or setting provider reimbursement rates, it could not have used this "reverse-engineered" information even had it been practical to do so. Finally, with respect to certain drugs, including several among the defendants' Subject Drugs, throughout the Relevant Time Period some manufacturers paid what are referred to as "Innovator Rebates," which were calculated by the federal government as the greater of either 1) the difference between the reported AMP for a drug and the manufacturer's Best Price; or 2) 15.1% of the reported AMP. Because California had no ability to confirm the means by which such Innovator

Rebates were calculated for these particular drugs, it had no ability to reverse engineer the AMP using the URA alone.

For these and other reasons, during the Relevant Time Period Medi-Cal had neither a practice nor policy of attempting to derive a drug's AMP as a function of its URA.

11. During the Relevant Time Period, defendants did not communicate to California a reasonable estimate of the average wholesale prices that providers paid for the Subject Drugs or the extent of the spreads between their reported AWPs and the prices being generally and currently paid by providers for the Subject Drugs. Similarly, at no time before or during the Relevant Time Period did defendants raise any questions or concerns with California regarding any federal or California report or study that cast doubt on the validity or accuracy of AWP as a pricing metric for Medicaid or Medicare reimbursement.

12. During the Relevant Time Period, neither I nor to the best of my knowledge any member of the Pharmacy Policy Section authorized defendants or any other manufacturers to report AWPs that exceeded good faith estimates of the amounts generally and currently being paid by providers for prescription drugs. Indeed, because the reimbursement standard was throughout the Relevant Time Period defined by statute and/or regulation, I did not believe that I or any other member of the Pharmacy Policy Section had the authority to authorize the reporting of AWPs that did not comply with applicable standards.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: November 23, 2009

J. KEVIN GOROSPE